

Attorney Docket No.: **DEX-0209**  
Inventors: **Salceda et al.**  
Serial No.: **09/886,241**  
Filing Date: **June 21, 2001**  
Page 5

#### **REMARKS**

Claims 3-7 are pending in the instant application. Claim 3 has been amended and claims 4-7 have been canceled. New claim 16 has been added. Support for amendments to the claims is provided in the specification at page 87, lines 6 through 22. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **Rejections under 35 U.S.C. §112, first paragraph - Lack of Enablement**

Claims 3-7 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner has acknowledged the specification to be enabling for determining levels of expression of SEQ ID NO:4 and for a method for diagnosing the presence of breast cancer in a patient comprising determining levels of a breast specific polynucleotide designated as SEQ ID NO:4 in cells, tissue or bodily fluids in a patient and comparing the determined levels of a polynucleotide comprising SEQ ID NO:4 or a polynucleotide encoding the same polypeptide in cells, tissue or bodily fluids from a normal human control, wherein a change in

Attorney Docket No.: **DEX-0209**  
Inventors: **Salceda et al.**  
Serial No.: **09/886,241**  
Filing Date: **June 21, 2001**  
Page 6

determined levels of a BSG polynucleotide comprising SEQ ID NO:4 or a polynucleotide encoding the same polypeptide as SEQ ID NO:4 is associated with the presence of breast cancer. However, the Examiner suggests that the specification does not reasonably provide enablement for determining the levels of the gene itself. Further, the Examiner suggests that the specification does not reasonably provide enablement for methods of diagnosing metastases, staging and monitoring changes in cancer.

Therefore, in an earnest effort to advance the prosecution of this case and in accordance with the Examiner's acknowledgment of enabled subject matter, Applicants have canceled claims 4-7 and amended claim 3 to be drawn to a method for detecting the presence of cancer in a patient comprising determining levels of a polynucleotide of SEQ ID NO:4 or a polynucleotide encoding a polypeptide encoded by SEQ ID NO:4 in cells, tissues or bodily fluids in a patient and comparing these determined levels with levels of the polynucleotide of SEQ ID NO:4 or polynucleotide encoding a polypeptide encoded by SEQ ID NO:4 in cells, tissues or bodily fluids from a normal human control, wherein a change in determined levels of the polynucleotide of SEQ ID NO:4 or polynucleotide encoding a polypeptide encoded by SEQ ID NO:4 in said patient versus normal human control is associated with the

Attorney Docket No.: **DEX-0209**  
Inventors: **Salceda et al.**  
Serial No.: **09/886,241**  
Filing Date: **June 21, 2001**  
Page 7

presence of cancer. Further, Applicants have added new claim 16 drawn to detection of breast cancer.

Support for detection of SEQ ID NO:4 or polynucleotide encoding a polypeptide encoded by SEQ ID NO:4 in breast cancer as well as other carcinomas is provided in the specification at page 87, lines 6 through 22. Detection of SEQ ID NO:4 and a polypeptide encoded thereby in other cancer types has been confirmed independently as well subsequent to the invention herein. See for example El-Rifai et al. Cancer Research July 15, 2002 62:4061-4064 and Beckler et al. Cancer October 1, 2003 98(7)1547-1551, copies of which are provided herewith.

Withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, for lack of enablement is respectfully requested in light of the amendments to the claims.

**IDS Submitted July 28, 2003**

Applicants submitted a Supplemental Information Disclosure Statement received by the United States Patent and Trademark Office on July 28, 2003. However, a signed copy of this Supplemental IDS by the Examiner evidencing her receipt and review was not attached with the other IDS forms provided with the instant Office Action. Accordingly, confirmation of receipt

Attorney Docket No.: DEX-0209  
Inventors: Salceda et al.  
Serial No.: 09/886,241  
Filing Date: June 21, 2001  
Page 8

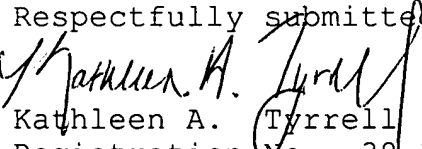
and review by the Examiner of the July 28, 2003 IDS is respectfully requested.

#### **Submission of Supplemental IDS**

Applicants are submitting herewith a further Supplemental Information Disclosure Statement for consideration by the Examiner along with the requisite. Confirmation of receipt of this Information Disclosure Statement and review of references cited therein is also respectfully requested.

#### **Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,  
  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: May 19, 2004

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
(856) 810-1515